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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,333	04/09/2004	Bret A. Shirley	PP17201.018 (035784/27729)	9990
27476 7590 09/14/2007 NOVARTIS VACCINES AND DIAGNOSTICS INC. INTELLECTUAL PROPERTY R338 P.O. BOX 8097 Emeryville, CA 94662-8097			EXAMINER SEHARASEYON, JEGATHEESAN	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 09/14/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/821,333	Applicant(s) SHIRLEY ET AL.	
	Examiner Jegatheesan Seharaseyon, Ph.D	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/12/2004 (resend)</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to Applicant's remarks and amendments filed 7/9/2007. Claims 1, 9, 15 and 20 have been amended. Claims 25 and 26 have been newly added. Therefore, claims 1-26 are pending and examined.

2. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

3. The Office notes that Applicant has amended the specification to remove embedded hyperlinks and capitalize trademarks. The specification also has been modified to provide SEQ ID Nos. In addition, Applicant has updated the priority information.

4. The Office acknowledges the receipt of the terminal disclaimer against 6, 887, 462.

5. The Office is enclosing a copy of the PTO-1449 with citation duly initialed.

Claim Rejections - 35 USC § 103, maintained

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6a. The rejection of claims 1-24 and 25-26 (newly added) under 35 USC § 103(a) as being unpatentable over Hershenson et al. (U.S. Patent No. 5, 004, 605) in view of Merck Index (1983), p. 121, column 2 is maintained for reasons set forth in the Office Action dated 4/2/2007 pages 4-5.

Applicant contends that the composition of the instant invention comprises substantially monomeric interferon-beta (IFN- β) or biologically active variant thereof solubilized in a low-ionic-strength formulation having an ionic strength that is not greater than about 20mM. In addition, the compositions have a pH of about 3.0 to about 5.0, plus or minus 0.5 units, and further comprising trehalose. Applicant submits that these compositions, and the methods for their preparation, are not taught or suggested by the Hershenson et al. patent, alone or in combination with the teachings of *The Merck Index*. Further, Applicant asserts that the Hershenson et al. formulations have an ionic strength that exceeds that of the presently claimed IFN- β compositions (not greater than about 20mM). In support of this assertion Applicant has calculated the ionic strength of the composition disclosed in Example 1, using Henderson-Hasselbach equation (see pages 17 and 18 of the response). Applicant's arguments have been fully considered but are not found to be persuasive. Although, Applicant has calculated the ionic strength disclosed in Example 1 to be 44.23mM, the prior art of Hershenson et al. teaches the buffer at a concentration to be about 10mM to about 25mM of phosphate buffer (see

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column 4, lines 58-59; claim 10). It is also noted that the ionic strength taught by the patent need not be the preferred embodiment in order to be obvious over the instant claims. In addition, MPEP 2144.05 [R-5] states that generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."). Therefore, optimization of the concentration of the buffer is considered obvious over prior art. Contrary to Applicant's assertion that the Hershenson et al. teaches away from instant invention, the reference does teach a buffer concentration of about 10mM to about 25mM of phosphate buffer.

Applicant is also arguing that the *Merck Index* reference does not teach or suggest its modification or combination with the teachings of Hershenson et al. to produce the compositions or methods of Applicants' claimed invention. Contrary to

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Applicant's assertion *Merck Index* teaches that aspartic acid has a pK_2 of 3.65. One of ordinary skill in the art use aspartic acid disclosed in the *Merck Index* to buffer the formulations taught by Hershenson because aspartic acid has optimal buffering capacity at the pH range taught by Hershenson reference. In addition, there is reasonable expectation of success because the Hershenson et al. discloses acids similar to aspartic acid as buffer in the composition. Therefore, Applicant's low ionic strength formulations are obvious over Hershenson et al. (U.S. Patent No. 5, 004, 605) in view of *Merck Index* (1983), p. 121, column 2.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7a. The rejection of claims 1-24 and 25-26 (newly added) on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 7-20 and 22 of copending Application No. 11/062, 146 ('146). Applicant's arguments with respect to nonstatutory obviousness-type double patenting have been fully considered but are not considered to be persuasive because '146 Application is still pending and there are other rejections of record which are maintained in the instant Application. Therefore, the rejection of record is maintained.

Conclusion

8. No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

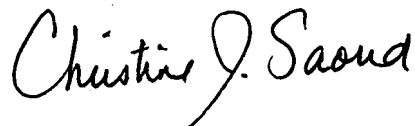
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS
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September 12th 2007

CHRISTINE J. SAOUD
PRIMARY EXAMINER

A handwritten signature in cursive script that reads "Christine J. Saoud".